REMARKS

Applicants thank Examiner Ebrahim for the courtesy of the phone interview on August 21, 2009. In the interview, Examiner Ebrahim and applicants' representatives Christopher Goff and Laura Hilmert discussed the rejection of claims 1-14 under 35 U.S.C. §102(b) over O'Connor, et al. (U.S. 2002/0045660), the rejection of claims 1, 5, and 11 under 35 U.S.C. §102(b) over Koletzko ("Fatty acids and early human growth," *Am. J. Clin. Nutr.*, 2001, Vol. 73:671-2), the rejection of claims 1, 5, and 10 under 35 U.S.C. §102(b) over Innis, et al., ("Docosahexaenoic acid and arachiodonic acid enhance growth with no adverse effects in preterm infants fed formula," *J. Pediat.*, May 2002, Vol. 140, No. 5, pp. 547-54), and the rejection of claims 1-16 under 35 U.S.C. §103(a) as being unpatentable over Innis, et al., in view of Koletzko, et al. ("Physiological aspects of human milk lipids," *Early Human Development*, 2001, 65 Suppl.:S3-S18), and further in view of O'Connor, et al.

In the interview, applicants argued that administering a nutritional formula comprising DHA and ARA to an infant does not inherently anticipate applicants' claim 1, which requires the nutritional formula be administered for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. Examiner Ebrahim disagreed, and took the position that any disclosure of administering a formula comprising DHA and ARA to an infant for the purposes of growth, or more specifically healthy growth, anticipated claim 1, since healthy growth encompasses increasing lean body mass and reducing fat body mass. Examiner Ebrahim indicated that the claims may be allowable if

amended to include the percent increase in lean body mass and/or the percent reduction in fat body mass at 12 months corrected age in preterm infants administered ARA and DHA containing formula as compared to preterm infants administered a control formula that does not comprise a source of ARA and DHA, as supported by the Example in the specification.

Status of Claims

Claims 1-17 are currently pending. Claims 1 and 16-17 have been amended, claims 10-11 have been cancelled, and new claims 18-22 have been added. Specifically, claims 1 and 17 have been amended as suggested by Examiner Ebrahim in the August 21, 2009 phone interview. Support for the amendment to claims 1 and 17 and for new claims 18-22 can be found in the Example in the Specification, and specifically on page 11, lines 20-28, page 12, lines 3-6, page 13, lines 21-28, page 18, lines 6-14, and in Table 6 on pages 25-26.

Supplemental Remarks on Claim Rejections

In addition to the remarks set forth Amendment B and Response After RCE, filed June 30, 2009, applicants request consideration of the following remarks.

As noted above, claim 1 has been amended to require the lean body mass of the preterm infant administered a nutritional formula comprising DHA and ARA from fish and fungal oil be increased by at least about 4% at 12 months corrected age as compared to preterm infants fed a control nutritional formula that does not comprise a source of DHA and ARA. Limitations relating to the percent

increase in lean body mass and/or the percent reduction in fat body mass are also present in amended claim 17 and new claims 18-22. Applicants submit that none of these limitations relating to the percent increase in lean body mass or the percent reduction in fat body mass are disclosed or suggested in any of the cited references.

§102(b) Rejections over O'Connor, et al.

As noted in applicants' previously filed response, the O'Connor, et al. reference states that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development. O'Connor does not, however, disclose or suggest that such formulas have any effect on body composition, such as increasing lean body mass or reducing fat body mass, or that the formulas should be fed to a premature infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. More specifically, there is no disclosure in O'Connor, et al. that ARA and DHA containing formulas can increase lean body mass and/or reduce fat body mass by the percentages set forth in applicants' amended claims. Applicants thus submit that claims 1-14 are novel over O'Connor, et al. for these reasons, in addition to the reasons set forth in Amendment B and Response After RCE, filed May 30, 2009.

§102(b) Rejections over Koletzko

As discussed in applicants' previous response, Koletzko states that infant formulas with a balanced supply of dietary ARA

and DHA did not lead to poor growth or otherwise adverse effects in several randomized clinical studies. There is, however, no disclosure in Koletzko that ARA and DHA containing formulas can increase lean body mass and/or reduce fat body mass by the percentages set forth in applicants' amended claims. Applicants thus submit that claims 1, 5, and 11 are novel over Koletzko for these reasons, in addition to the reasons set forth in Amendment B and Response After RCE, filed May 30, 2009.

§102(b) Rejections over Innis, et al.

Similar to O'Connor, et al., the Innis, et al. reference evaluated the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants, but failed to suggest that such formulas increase lean body mass and reduce fat body mass, or that the formulas should be fed to an infant for this purpose. Furthermore, there is no disclosure in Innis, et al. that ARA and DHA containing formulas can increase lean body mass and/or reduce fat body mass by the percentages set forth in applicants' amended claims. Applicants thus submit that claims 1, 5, and 10 are novel over Innis, et al. for these reasons, in addition to the reasons set forth in Amendment B and Response After RCE, filed May 30, 2009.

§103 Rejections over Innis, et al., Koletzko, et al., and O'Connor, et al.

The Innis, et al. and O'Connor, et al. references are discussed above. Additionally, the Koletzko, et al. reference generally discusses the physiological aspects of human milk

lipids, and notes that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies. Koletzko, et al., however, fails to disclose or suggest that infant formulas including both ARA and DHA have any effect on lean body mass and fat body mass. More specifically, there is no disclosure in Koletzko, et al. that ARA and DHA containing formulas can increase lean body mass and/or reduce fat body mass by the percentages set forth in applicants' amended claims.

Thus, the requirement in applicants' amended claims relating to the percent increase in lean body mass and/or the percent reduction in fat body mass in preterm infants fed a nutritional formula comprising DHA and ARA (whether from fish oil, fungal oil, and/or egg-derived triglycerides) is entirely lacking from the cited references. In contrast, as clearly set forth in the specification of the instant application, applicants have discovered that infants fed a nutritional formula comprising DHA and ARA, or a suitable source thereof, can increase lean body mass and reduce fat body mass as compared to an unsupplemented control formula, without having an impact on the rate of overall growth of the infant.[1] None of the cited references disclose or recognize that the combination of DHA and ARA has any effect on body mass, or more specifically can result in applicants' claimed percentage increase in lean body mass and reduction in fat body mass in preterm infants at 12 months corrected age. Given this lack of disclosure and recognition, there would be no motivation to modify the teachings of the cited references to arrive at applicants'

[1] *See* Specification at p. 2, lines 13-16 and 24-27 and Example.

claimed methods. Applicants thus submit that claims 1-16 are patentable over Innis, et al., Koletzko, et al, and O'Connor, et al. for these reasons, in addition to the reasons set forth in Amendment B and Response After RCE, filed May 30, 2009.

CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-16 and allowance of all pending claims. The Commissioner is hereby authorized to charge any required government fees to Deposit Account No. 01-2384.

Respectfully Submitted,

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